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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,650	07/31/2003	Thomas Piccariello	54719.000051	7775

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
SOROUSH, LAYLA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,650	PICCARIELLO ET AL.	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Office Action is in response to the Preliminary Amendment filed July 31, 2003. This application is a CIP of 09/440,635 (11/16/1999) PAT 6,627,660.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, 17-18, 22-24, 28-29, 33-34 and 38-40 drawn to a composition comprising a triiodothyronine protected at a phenolic hydroxyl with a protecting group said protecting group selected from the group consisting of dialkylphosphinate, diarylphosphinate, alkylarylphosphinate, dialkylphosphate, diarylphosphate, aklylarylphosphate, acetyl, trialkylsilyl, and benzyloxy carbonyl, classified in class 514, subclass 567.

II. Claims 14, 15, 19, 20 25, 26 30, 31, 35 and 36 drawn to method of treating a thyroid related condition comprising treating a patient in need thereof with the composition comprising a triiodothyronine protected at a phenolic hydroxyl with a protecting group said protecting group selected from the group consisting of dialkylphosphinate, diarylphosphinate, alkylarylphosphinate, dialkylphosphate, diarylphosphate, aklylarylphosphate, acetyl, trialkylsilyl, and benzyloxy carbonyl, classified in class 514, subclass 567.

III. Claim 16, 21, 27, 32, and 37 drawn to method of stabilizing and increasing the shelf life of a thyroid hormone comprising a composition of triiodothyronine protected at a phenolic hydroxyl with a protecting group

said protecting group selected from the group consisting of dialkylphosphinate, diarylphosphinate, alkylarylphosphinate, dialkylphosphate, diarylphosphate, aklylarylphosphate, acetyl, trialkylsilyl, and benzyloxy carbonyl, classified in class 514, subclass 567.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a method of treating a thyroid related condition, e.g. hyperthyroidism, can be treated with a different product e.g., dl-tetrahydropalmatine.

Because these inventions are distinct for the reasons given above and the search required for Groups Inventions I is not required for Groups II restriction for examination purposes as indicated is proper. The searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. In searching Groups Inventions I, Examiner will be focusing on the patentability of the composition itself, and not the method of treating a thyroid related condition of Group II. Conversely, in searching Group II, Examiner will be focusing on the patentability of the method of treating a thyroid related condition and not the composition itself. Thus, Groups I and II have been appropriately restricted on the basis

of being independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a method of stabilizing and increasing the shelf life, can be used with a different product, e.g., polymers (US Pat No. 5683993). .

Because these inventions are distinct for the reasons given above and the search required for Groups I is not required for Groups III, restriction for examination purposes as indicated is proper. The searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. In searching Groups I, Examiner will be focusing on the patentability of the composition itself, and not the method of stabilizing and increasing the shelf life of Groups III. Conversely, in searching Groups III, Examiner will be focusing on the patentability of the method of stabilizing and increasing the shelf life and not the composition itself. Thus, Groups I and III have been appropriately restricted on the basis of being independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because Groups Inventions II are directed to a method of treating a thyroid related condition, whereas Group III is directed to a method of stabilizing and increasing the shelf life of a thyroid hormone. The methods have different functions and effects. The inventions are also not disclosed as capable of use together, because the steps involved in the process of treating and the process of stabilizing and increasing the shelf life of a thyroid hormone are different. That is, the steps of stabilizing and increasing the shelf life of a thyroid hormone are not taught as being equivalent to, or useful as, steps performed for the purpose of treating a thyroid related condition, and vice versa.

Because these inventions are distinct for the reasons given, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups II and III may be overlapping, there is no reason to believe that the searches are co-extensive. In searching Groups II, the Examiner will be focusing on the patentability of the method of treating a thyroid related condition and not the process of stabilizing and increasing the shelf life of a thyroid hormone of Groups III. Conversely, in searching Group III, the Examiner will be focusing on the patentability of the method of stabilizing and increasing the shelf life of a thyroid hormone. Accordingly, a search for both groups would pose an undue burden on the Office.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention: triidothyronine protected at a phenolic hydroxyl with

various protecting groups (claims 1-16, and 38-40), reverse triidothyronine protected at a phenolic hydroxyl with various protecting groups (claims 17-21 and 38-40), 3,5 diiodothryonine protected at a phenolic hydroxyl with various protecting groups (claims 22-27 and 38-40), 3-monoiodothyronine protected at a phenolic hydroxyl with various protecting groups (claims 28-32 and 38-40), and a thyroxine protected at a phenolic hydroxyl with various protecting groups (claims 33-37 and 38-40).

If applicant chooses the triidothyronine protected at a phenolic hydroxyl with various protecting groups (claims 1-16, and 38-40) to be examined on the merits; Applicant is required to further elect a single species of the triidothyronine protected at a phenolic hydroxyl with one protecting group. If applicant chooses reverse triidothyronine protected at a phenolic hydroxyl with various protecting groups (claims 17-21 and 38-40) to be examined on the merits; Applicant is required to further elect a single species of reverse triidothyronine protected at a phenolic hydroxyl with one protecting group. If applicant chooses the 3,5 diiodothryonine protected at a phenolic hydroxyl with various protecting groups (claims 22-27 and 38-40) to be examined on the merits; Applicant is required to further elect a single species of the 3,5 diiodothryonine protected at a phenolic hydroxyl with one protecting group. If applicant chooses the 3-monoiodothyronine protected at a phenolic hydroxyl with various protecting groups (claims 28-32 and 38-40) to be examined on the merits; Applicant is required to further elect a single species of 3-monoiodothyronine protected at a phenolic hydroxyl with one protecting group. If applicant chooses the a thyroxine protected at a phenolic hydroxyl with various protecting groups (claims 33-37 and 38-40) to be examined on the merits;

Applicant is required to further elect a single species of a thyroxine protected at a phenolic hydroxyl with one protecting group.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims of Groups I-III read on various compounds with various protecting groups, the search for all of which presents an undue burden on the Office.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

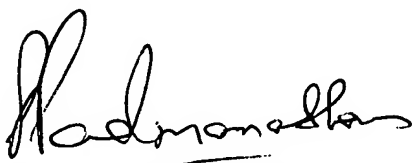
A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP 812.01). Since the restriction election is considered complex, a call to the attorney for a telephone election was not made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER